



SoCalBio
Southern California
Biomedical Council

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The Southern California Biomedical Council (SCBC) is the trade association of the Greater Los Angeles Life Sciences industry. The mission of the SCBC is to promote and support life-science research, development and manufacturing in Greater Los Angeles for job creation and economic growth.

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SoCalBio Symposium

April 26, 2007

7:30 am to 3:30 pm

Board Room @ Los Angeles Chamber of Commerce
350 S. Bixel Street, Los Angeles, CA 90017

New Developments in Life-Science IP Law

This symposium is designed for life-science companies to implement best practices and successful methodologies in building and protecting intellectual property assets.

Sponsored by



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A L A W C O R P O R A T I O N

Agenda

7:45 am	Ahmed Enany, Southern California Biomedical Council, “Introduction”
CRITICAL ISSUES TO CONSIDER WHEN BUILDING A ROBUST IP PORTFOLIO	
8:00 am	Chris Fugelsang, Ph.D., Tavistock Life Sciences, “Determining when R&D should turn into IP and when patents are commercially viable”
8:30 am	Michael Wise, Partner, Perkins Coie, “Issues to consider when crafting a patenting strategy”
9:15 am	James Zhu, Ph.D., Partner, Perkins Coie, “Claim construction in the post-Phillips vs. AWH case”
9:45 am	Lisa Karczewski, Attorney, Chan Law Group, “Securing freedom to operate for research activities: the Merck KGAA vs. Integra case”
10:15 am	Ron Carlson, Sr. VP, USI, “IP risk management”
10:30 am	Networking break



CRITICAL ISSUES TO CONSIDER WHEN LICENSING IP

- 11:00 am Scott Carter, Ph.D., Attorney, Latham & Watkins, **“The dos and don’ts of licensing – part I”**
- Licensing in the wake of the recent MedImmune vs. Genentech
 - IP ownership in collaborations:
 - invoking the CREATE Act
 - the lessons of Israel Bio-Engineering vs. Amgen
 - Licensing from universities under Bayh-Dole
 - Patent trolling as a business strategy

- 11:30 am Robert Berliner, Founder, Berliner & Associates, **“The dos and don’ts of licensing – part II”**
- Construction and enforcement of confidentiality agreements
 - On paying royalties based on the “entire market value rule”

- 12:00 noon **Lunch & keynote presentation by serial entrepreneur and inventor:**



Dr. William Rassman
Chairman, Maven Biotechnologies
President, New Hair Institute

BRACING FOR THE IMPACT OF PATENT REFORM ON PATENT PORTFOLIO MANAGEMENT IN THE LIFE-SCIENCE INDUSTRY

- 2:00 pm Jeffrey Craft, Shareholder, Jackson, DeMarco, Tidus & Peckenpaugh, **“Nervous anticipation of the High Court’s ruling on the “Obviousness Test”**
- The “obviousness” issue is rooted in an obscure patent dispute about gas pedal designs between the Canadian firm KSR International and Pennsylvania-based Teleflex. However, it has attracted the attention of life-science firms because it addresses one of the fundamental questions in patent law: what makes an invention (particularly a combination of existing parts) too “obvious” to warrant protection? If the Supreme Court decides to rewrite the legal standard of “obviousness” to make it more restrictive, it could reshape U.S. intellectual property law. A decision is expected by July 2007.
- 2:30 pm Kristin Kosinski, Attorney, Davis Wright Tremaine, **“IP consequences of recent legislation concerning biosimilars”**
1. Current landscape of abbreviated process for generic biologics in the U.S. and Europe
 2. Sandoz case regarding approval of Omnitrope, a recombinant human growth hormone drug
 3. Impact of U.S. Congress’ proposed “Access to Life-Saving Medicine Act.” This act seeks to create a safe, clear and efficient abbreviated FDA approval pathway so patients can have timely access to biogenerics.
 4. Crafting IP strategy in view of this landscape
- 3:00 pm Rod Berman, Chairperson of the Intellectual Property Department, Jeffer, Mangels, Butler & Marmaro, **“Patent reform and the future of the patent system”**
- Assessing the likely unintended consequences of patent reforms -- as proposed for example in the 2007 Patent Reform Act -- on changing the standards for:
1. Continuation practice
 2. Inequitable conduct
 3. Willful infringement
 4. Injunctive relief, and
 5. Select district court judges

- 3:30 pm **Symposium Adjourns**

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Davis Wright Tremaine LLP is a law firm with Northwest roots and national reach. A business and litigation law firm with more than 480 attorneys, DWT has nine offices in Seattle, Bellevue (Wash.), Portland (Ore.), Anchorage (Alaska), Los Angeles, San Francisco, New York, Washington D.C. and in Shanghai, China. For more information about DWT and its services, visit www.dwt.com.

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About Speakers

By order of presentations

Chris Fuglesang, Ph.D.
Tavistock Life Sciences
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Dr. Fuglesang joined Tavistock Life Sciences in 2005. He has responsibilities for portfolio intellectual property, the management of existing portfolio companies, and the identification of prospective public and private investments. Prior to joining Tavistock, Dr. Fuglesang was Vice President at Eidogen, a structural proteomics software company, and a practicing attorney at Perkins Coie LLC in their biotechnology practice group.

Education:

- J.D. from Boston University.
- Ph.D. in Theoretical Chemical Physics from the University of California at Los Angeles
- B.S. in both Chemistry and Physics from the University of California at Los Angeles

Michael Wise, Partner
Perkins Coie

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Michael Wise is a partner and chairs Perkins Coie's China Intellectual Property practice. He focuses on patent matters in the life sciences industry. Michael serves as lead counsel in biotech litigation and interference matters, provides legal opinions regarding patents and manages a diverse portfolio of patent applications. Michael represents a broad range of life sciences clients from large established companies such as Schering Plough to research institutions such as the National Institutes of Health. Michael also represents a number of venture capital firms and venture capital funded start-up companies. Michael chaired the SoCalBio annual investment conference targeting early stage life sciences companies.

Michael leads Perkins Coie's effort to establish a life sciences-focused practice in China. Michael has chaired panel discussions on China and introduced the Chinese delegation to BIO 2004, 2005 and 2006. Michael is frequently invited to speak and write about China-related IP matters.

Education:

- Loyola Law School, Los Angeles, J.D., cum laude, Order of the Coif, 1989
- University of California, Los Angeles, B.S., Biology, 1985

James Zhu, Ph.D., Partner
Perkins Coie

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James is a partner in Perkins Coie's IP group and is one of the key members in the firm for establishing the Shanghai Office. James' practice focuses on patent procurement, patent opinion, patent due diligence, intellectual property infrastructure, patent litigation, technology

licensing, primarily in the fields of life sciences, medical device, chemical industry, and material sciences

James is a frequent author and speaker for various IP related subjects. James has been actively involved with the Biotechnology Industry Organization (BIO) where he has served as a delegation committee member since 2004 and introduced/promoted the presence of the Chinese delegation and pavilion in the BIO annual meetings. James is also a board member for BayHelix Group and Chinese Biological Investigator Society (Wu-Ray Society).

Education:

- Columbia University School of Law, J.D., 1999
- Columbia University, M.B.A., 1999
- California Institute of Technology, Ph.D., Cellular and Molecular Biology, 1994
- Fudan University, B.S., Biology, 1986

Lisa A Karczewski, Associate

Chan Law Group

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Ms. Karczewski focuses her practice on intellectual property litigation and patent and trademark prosecution. With seven years of experience in the specialty of intellectual property law, Ms. Karczewski has successfully prepared and prosecuted over fifty utility patent applications in the technical areas of aerospace, biomedical, biopharmaceuticals, chemical, life sciences, and mechanical, before the U.S. Patent & Trademark Office. Ms. Karczewski has also successfully litigated intellectual property cases in the federal courts as a member of the Firm's litigation team.

Education

- Juris Doctorate, *with distinction*, Intellectual Property Law Concentration, University of the Pacific, McGeorge School of Law, 2000
- Bachelor of Science, Biological Sciences, Michigan State University, 1992

Ronald Carlson, Sr. VP

USI

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Career History:

1995 to Present	USI of Southern California Insurance Services
1977 – 1995	United California Insurance Agency
1975 – 1977	Industrial Indemnity Insurance Company
1972 – 1975	Atena Life & Casualty Insurance Company

Education:

- Executive MBA, Boston University
- American Institute for Chartered Property Casualty Underwriters
- BA, Marietta College

Scott Carter, Ph.D., Associate
Latham & Watkins
(213) 891.8294 -- scott.carter@lw.com

Prior to joining Latham & Watkins, Dr. Carter was the Assistant Director of the Office of Technology Transfer at the California Institute of Technology (Caltech). Dr. Carter managed Caltech's Life Science patent portfolio and negotiated and drafted license agreements, research agreements and material transfer agreements. He also advised Caltech entrepreneurs on starting high-tech ventures.

Dr. Carter is registered to practice before the United States Patent and Trademark Office, and prior to his work at Caltech, prosecuted biotech patent applications and provided technical consultation on patent litigation for a California law firm. He graduated summa cum laude from Amherst College with a degree in Biochemistry. Dr. Carter received a Ph.D. in Chemistry from Caltech in the laboratory of Peter Dervan, where his research focused on the design, synthesis and testing of DNA binding molecules.

Dr. Carter has been a frequent speaker on intellectual property and university technology transfer, including a PLI biotechnology course.

Education:

- JD, Univ. of California, Los Angeles, 2006
- Ph.D, California Institute of Technology, 1998
- BA, Amherst College, 1992

Robert Berliner, Founder
Berliner & Associates
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Bob Berliner was a founding member of the intellectual property firm of Robbins, Berliner & Carson L.L.P. for more than 25 years, becoming a partner of the international general law firm of Fulbright & Jaworski L.L.P. following the 1997 merger of the two firms.

Having decades of practice in all aspects of intellectual property, and having developed a network of over sixty top rated intellectual property firms in more than twenty countries, he formed Berliner & Associates as a full service intellectual property firm specializing in patent, trademark and copyright prosecution, licensing and litigation, both in the United States and worldwide.

He has close familiarity with the special needs of University patent portfolios, and in assisting in the formation and operations of early stage companies. He has patent expertise in many fields, including organic and inorganic chemistry, polymers, chemistry, biotechnology, solid state electronics, physics, optics, and biomedical and other mechanical devices.

Education:

- J.D. in 1960 from Michigan State University.
- B.S. in 1956 from The City College of New York

William Rassman, M.D.

**Maven Biotechnologies
& New Hair Institute**

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Dr. William R. Rassman received his Doctor of Medicine from the Medical College of Virginia in 1966. He completed a surgical internship at the University of Minnesota and obtained a cardiovascular fellowship with Dr. C.W. Lillehei.

Dr. Rassman completed his residency in general surgery at the Cornell Medical Center and Dartmouth Medical Center. He served as a Major in the U.S. Army, and was stationed as a surgeon in the Republic of Vietnam.

Dr. Rassman was certified by the American Board of Surgery in 1976.

Dr. Rassman was a major researcher in the cardiac field commercializing the Intra-Aortic Balloon Pump in 1969, a device credited with saving thousands of lives annually. He also holds multiple patents in other medical devices, computer software, and, more recently, in the biochip field, an area where he has great interest.

As a professional inventor with multiple U.S. and worldwide patents, Dr. Rassman has 30 years of managerial and executive experience with numerous medical groups and various companies in the sciences through start-up and sale. Examples include the New Hair Institute (NHI), which was founded in 1991 and quickly became a world leader in hair restoration surgery and in hair transplant technology. He also founded Maven Biotechnologies in 2000 to develop label-free, high density imaging system for quantitative biomarker analysis that can characterize molecular binding reactions in real-time.

In all fields he has pioneered new techniques, published articles in prestigious medical journals, presented scientific papers before national and international societies and continues to push the 'state-of-the-art' to new heights.

Herbert Shapiro

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Mr. Shapiro is a retired patent attorney. He worked at Bell Labs for 27 years primarily in the semiconductor, magnetic and software technologies.

He has been involved in two start-up companies TRIZ which helped new companies get off the ground and a Russian company "Invention Machine" which had methodologies for Inventive Problem Solving.

Mr. Shapiro has written and prosecuted hundreds of patent applications and holds a number of patents as well. He consults with several companies now, dealing with patent process more manageable.

Jeffrey F. Craft, Shareholder
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Mr. Craft has been involved in all aspects of the protection of intellectual property, since 1981, with an emphasis on intellectual property litigation, as well as client counseling and the preparation and prosecution of patent and trademark applications. His experience extends to design and management of technology portfolios, ownership and inventorship issues, appeals and oral hearings, reissues, reexaminations, negotiations, licensing and agreements drafting due diligence studies, freedom to market, patentability, validity, and infringement opinions.

Mr. Craft has particular expertise in chemistry, biochemistry, life sciences, and chemical engineering and he has worked in the areas of medical applications, pharmaceuticals, plant technology, biotechnology, genetics, molecular biology, polymers, semiconductors, solid electrolyte batteries, fuel cells, injection molding, waste treatment and a wide range of food and agricultural technologies.

Education:

- Wayne State University (J.D., 1981)
- University of Michigan (B.S., 1976)

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Ms. Kosinski focuses her practice on all aspects of intellectual property law, including patent prosecution, client counseling, and licensing in the biotechnology, pharmaceutical, and chemical areas. She has particular expertise in the intersection of patent law and FDA drug approval.

Ms. Kosinski has prepared opinions and prosecuted patents directed to pharmaceuticals, biotechnology, biological processes, and various other technologies. She has also assisted clients with trademark, domain name, copyright, privacy, and regulatory compliance issues.

Education:

- J.D., Seton Hall University School of Law, 2001
- B.A., in Biology, magna cum laude, Drew University, 1998

Rod S. Berman , Partner
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As chairperson of the Firm's Intellectual Property Law Group, Rod Berman's practice emphasizes patent, trademark, copyright and unfair competition responsibilities, including counseling, litigation, opinions, licensing and prosecution. He represents many nationally and internationally known clients, and has been involved in a number of published patent, trademark and copyright cases in a wide variety of industries.

Rod has worked on a broad range of matters including those involving pharmaceuticals, biotechnology, computer-related business methods, dietary and nutritional supplements, food and restaurants, apparel, beauty care, polymers, pressure sensors, inflatables, medical devices, bicycles, jewelry, packaging, automotive, sports and entertainment, special effects, toys, insecticides and retail.

In addition to being a registered patent attorney, Rod is a court-recognized expert in patent and trademark law, and has successfully argued before the Federal Circuit.

Education:

- J.D., cum laude, Loyola Law School, Loyola Marymount University, 1982, top 4%
- M.S., Chemistry, Indiana University, Ph.D. candidate, 1979
- B.S., Chemistry, University of California, Los Angeles, 1977